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February 12, 2019

VIA CERTIFIED MAIL & E-mail

Stephanie L. Parker Clifton Parker Restore Robotics LLC 1275 Buford Hwy, Suite 109 Suwanee GA 30024 <u>cparker@restorerobotics.com</u> <u>bmcdaniel@restroerobotics.com</u> info@restorerobotics.com

Subject: Tampering with and Reprogramming da Vinci® Surgical System Instruments; Improper System maintenance

Dear Ms. Parker and Mr. Parker,

We write on behalf of Intuitive Surgical, Inc. ("Intuitive"), a company that develops and distributes advanced robotic-assisted surgical platforms for minimally-invasive surgery. Our core products include the *da Vinci*® Surgical System (the "System") as well as the *EndoWrist*® instruments that attach to the System.

It has come to our attention that Restore Robotics LLC ("Restore Robotics") is engaging in the unauthorized manufacturing and marketing of a medical device

We also have concerns that the devices potentially being distributed are not being manufactured, or re-manufactured as the case may be, under a recognized quality management system applicable to medical devices. In addition, we believe that Restore Robotics has engaged in behavior that violates applicable laws and may give rise to civil liability. We write to you on behalf of Intuitive to demand that Restore Robotics immediately cease and desist from any and all improper behavior with regard to the *EndoWrist®* instruments, including but not limited to your actions described below.

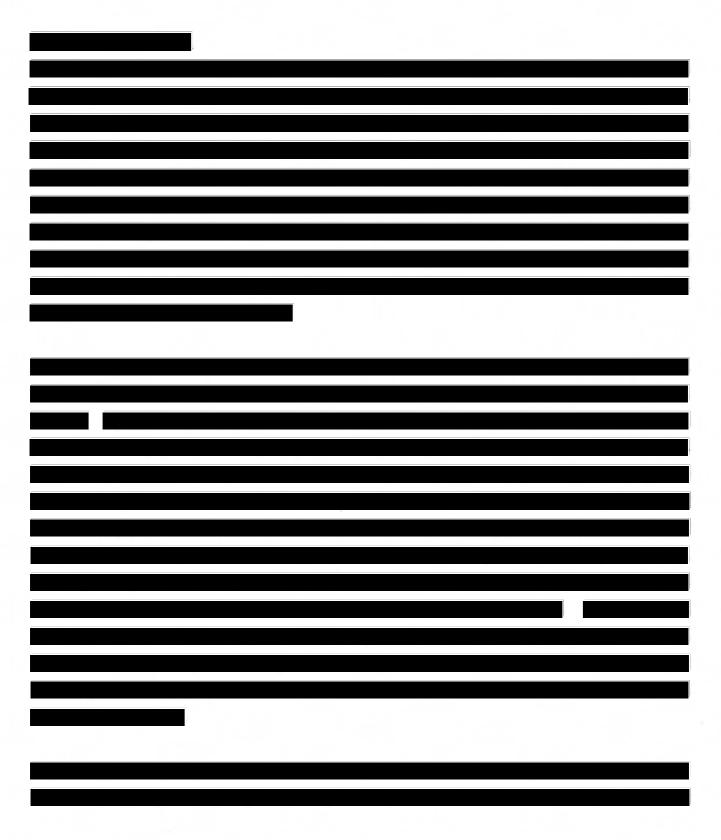
INTUÎTIVE.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

TRIAL EXHIBIT 1635.014-R

Case No. _3:21-cv-03496-AMO
Date Entered_____
By_____
Deputy Clerk

Restore-00025577

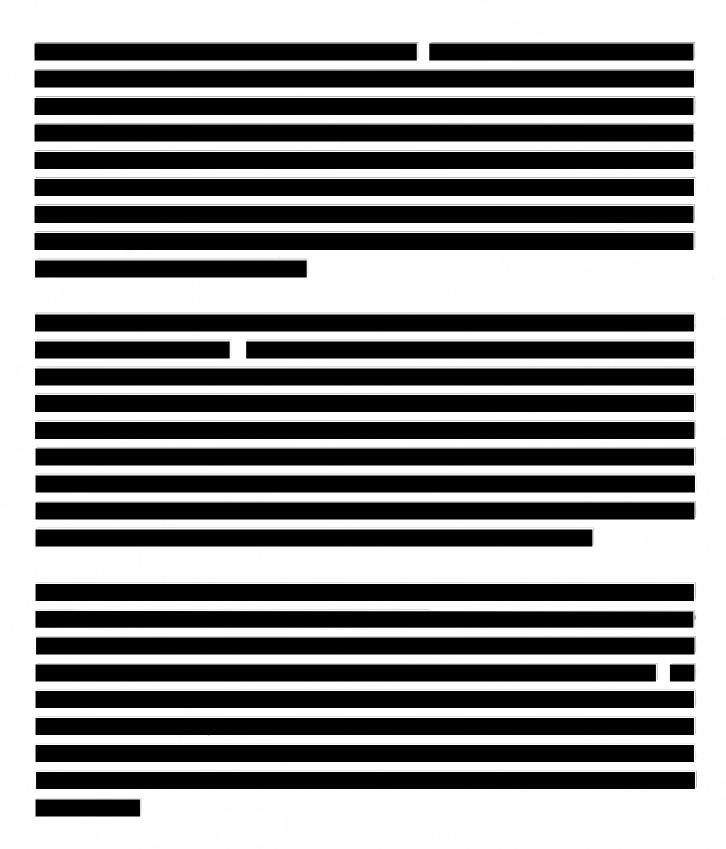


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Factual Background
In accordance with its quality system, Intuitive engages in rigorous testing
. Generally, and specifically with respect to the EndoWrist®
instruments, that includes instrument reliability/projected life testing to confirm the maximum number
of safe and effective clinical uses of a product prior to disposal.
. With respect to many of the EndoWrist® instruments,
Intuitive Surgical determined – ten surgical procedures is the
maximum number of safe and effective clinical uses prior to disposal. Accordingly, Intuitive placed a
memory device inside such instruments that keeps track of the usage count and inhibits the instrument
from functioning after ten uses.
We recently have become aware that you are offering Intuitive customers in the United States a type of
"testing and repair" service for the <i>EndoWrist®</i> instruments. We understand that you are informing our
customers that, rather than discarding the instruments after ten clinical uses, they can send you the
instruments "that have only 1 use left" and you will clean and "utilize [y]our proprietary and patented
process to restore the available uses to its original state."
Restore Robotics' Alleged Activities Violate U.S. Law
We have numerous concerns with the foregoing activities. First, it is unclear whether you or your
service technicians have the requisite specifications by which to make the claim that the units are
returned to their production equivalent qualification. Even assuming for argument that you have
obtained these specifications, or Intuitive's service manual, any modifications that reset or extend the
number of uses of the device. This change impacts the intended use of
the device, exceeds the verified and validated testing
constitutes a major change to the device.

CONFIDENTIAL Restore-00025579

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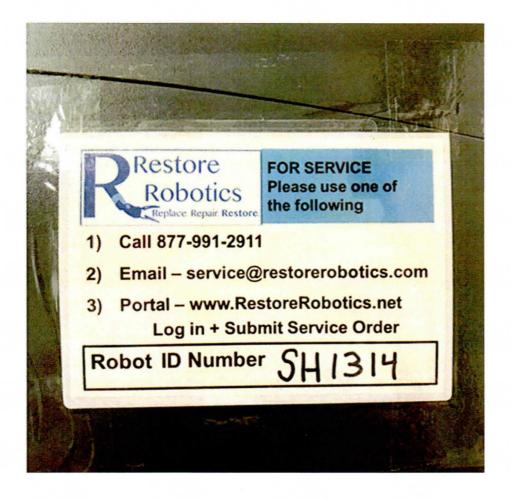
Lastly and most critically, Restore Robotics' modification of the *EndoWrist®* instruments impacts the intended use of the device, exceeds the verified and validated testing performed by Intuitive to another the clinical use of such modified instruments in surgical procedures. For this reason, you could face significant financial liability from both practitioners and their patients in connection with your untested, unapproved modification of the *EndoWrist®* instruments.

Improper System Servicing Puts Patient Safety at Risk

Restore Robotics is offering and purporting to provide maintenance service to hospital customers on *da Vinci*® Surgical Systems even though you may not have the tools and knowledge necessary for proper system maintenance, potentially jeopardizing patient safety.

At one hospital, Restore Robotics' sticker appears on a System that appeared to have been "serviced" by you.

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After such service at a hospital, a surgeon complained about the vision system not working properly and had to reschedule a surgery until the system was properly repaired. Our inspection revealed that vision cables on the boom had been improperly reconnected, the left and right video cables had been crossed, thereby compromising the 3D vision provided to the surgeon. In another instance, third-party personnel (potentially your service personnel) were observed trying to use a da Vinci S sterile adapter to connect an Si scope to its camera head. This could negatively affect scope performance and compromise the sterile field around the patient and members of the surgical team. These are a cause for patient safety concerns.

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Demand

Based on the foregoing apparent violations of U.S. law, Intuitive demands that Restore Robotics immediately cease and desist from:

- a. marketing and offering a servicing process in the course of which the use counter of *EndoWrist®* instruments' memory device is manipulated and/or replaced to permit more than ten uses;
- b. contacting Intuitive's customers to offer services related to Intuitive's products; and

c.

Please confirm your compliance with these demands no later than February 28, 2019. If you allege that you

possess clinical proof that your service process returns the modified instruments to a "production equivalent qualification" and/or that additional use does not affect the safety or performance of the instruments, provide proof of the same no later than February 28, 2019.

We reserve all rights to take all appropriate action against you and to protect Intuitive's rights, products and reputation, including

pursuing appropriate civil remedies.

Very truly yours,

Romain Denis

VP, EU and US Regulatory Affairs

Kara Andersen Reiter

SVP, General Counsel & CCO

CC

Parker Holding Group, Inc. (Registered Agent), 2933 Fairmont Drive, Panama City, FL 32405
Restore Medical Repair LLC, 2933 Fairmont Drive, Panama City, FL 32405
Clifton Parker, Authorized Person, Restore Robotics, LLC, 2933 Fairmont Drive, Panama City

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Restore Robotics Repairs LLC, 2933 Fairmont Drive, Panama City, FL 32405

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